

DEC - 5 2003

**510(k) Summary of Safety and Effectiveness
for Galt Medical's Hydrophilic Coated Vascular Guidewires**
(Prepared in accordance with 21 CFR Part 807.92)
Date 11/18/03

- (1) **Submitter:** Galt Medical Corp.
2475 Merritt Drive
Garland, TX 75041
(972) 271-5177
Contact Person: David Catlin
- (2) **Device Name: Guidewire**
Trade Name: Easy Pass Hydrophilic Coated Vascular Guidewire
Classification Name: Wire, Guide, Catheter
Classification Code: DQX
- (3) **Substantial Equivalency:** Galt Medical Corp. guidewires are substantially equivalent to guidewires from K982559, K021990, and K031916
- (4) **Device Description:** The materials of construction stainless steel, nitinol, platinum are consistent with guidewires presently in commercial distribution. The wires are available straight, angled or with "J" end. The wires range from .014" diameter through .065" diameter and lengths from 20cm. to 360 cm. The wires are coated with a plastic hydrophilic or hydrophilic coating.
- These guidewires are intended for use in percutaneous procedures to introduce and position catheters, pacing leads and other interventional devices within the coronary and peripheral vasculature.
- (5) **Technological Characteristics:** Galt Medical's guidewires have the same indications for use and are otherwise technically the same as the predicate devices.
- (6) **Conclusions:** Based on the information presented in this 510(k) premarket notification, Galt Medical's hydrophilic coated vascular guidewires are considered substantially equivalent to the currently marketed predicate devices.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Galt Medical Corporation
c/o Mr. David G. Catlin
Executive Vice President
2475 Merrit Drive
Garland, TX 75041-6146

Re: K033542
Hydrophilic Coated Vascular Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guide wire
Regulatory Class: Class II
Product Code: DQX
Dated: November 6, 2003
Received: November 10, 2003

Dear Mr. Catlin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

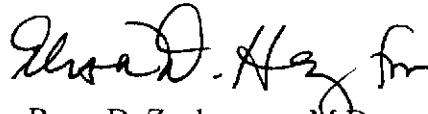
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address

<http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman".

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number (if known): 1633542

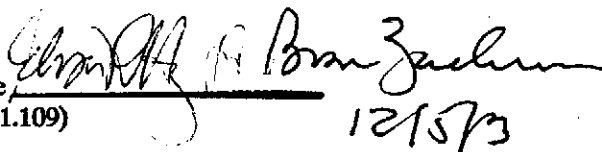
Device Name: Hydrophilic Coated Vascular guidewire

Indications For Use: These guidewires are intended for use in percutaneous procedures to introduce and position catheters, pacing leads, and other interventional devices within the coronary and peripheral vasculature.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)


12/5/03

Prescription Use X

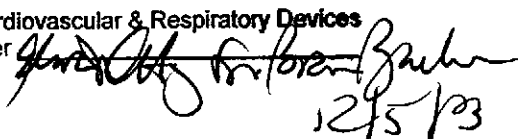
OR

Over-the Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number


12/5/03